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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Sandoz Inc. and RareGen, LLC *Plaintiffs*, v. United Therapeutics Corporation and Smiths Medical ASD, Inc. *Defendants*.	Case No. _____ **COMPLAINT** **JURY TRIAL DEMANDED**

INTRODUCTION

1. Defendants United Therapeutics Corporation ("United Therapeutics") and Smiths Medical ASD, Inc. ("Smiths"), in violation of the Sherman Act, are unlawfully impeding competition from a new generic drug that treats pulmonary arterial hypertension ("PAH").

2. PAH is a life-threatening disease that causes high blood pressure in the arteries that run from the heart to the lungs. Many PAH patients need medical devices that are manufactured by Smiths (single-use cartridges that are specifically designed for the infusion pumps manufactured by Smiths) to receive subcutaneous injections of a life-saving drug called treprostinil.

3. Plaintiffs Sandoz Inc. ("Sandoz") and RareGen, LLC ("RareGen") recently introduced the first generic form of treprostinil that can be administered through subcutaneous injections.

4. In an effort to thwart the launch of that product and to maintain higher prices, Defendants placed artificial restrictions on Smiths' cartridges to ensure they can only be used to administer injections of the brand-name treprostinil drug supplied by United Therapeutics, which is called Remodulin®. Defendants have instructed the pharmacies dispensing treprostinil that they are prohibited from purchasing or dispensing Smiths' cartridges for use with generic treprostinil. And Smiths has committed to sell its entire supply of cartridges to United Therapeutics

(or other purchasers that are specifically approved by United Therapeutics).

5. Defendants' anticompetitive conduct has allowed them to control access to treprostinil for subcutaneous injections and enabled them to maintain higher prices for that critical treatment.

6. The anticompetitive restrictions imposed by Defendants have no public benefit or medical justification—they merely protect United Therapeutics' bottom line. During the last three calendar years, Remodulin® generated $599.0 million, $670.9 million, and $602.3 million in net product sales for United Therapeutics, which represented more than 35% of the company's total revenues in each of those years. Absent Defendants' anticompetitive conduct, that entire franchise would now be under attack by Plaintiffs' generic alternative, which is substantially cheaper than Remodulin®.

7. Sandoz and RareGen bring this action under federal and state law to: (1) enjoin Defendants from denying PAH patients access to the cartridges they need to receive subcutaneous injections of generic treprostinil; and (2) obtain relief for the injuries they have suffered as a result of Defendants' anticompetitive conduct.

THE PARTIES

8. Plaintiff Sandoz sells generic and biosimilar medicines. Sandoz is committed to playing a leading role in providing patients with access to affordable medications. Sandoz is incorporated under Colorado law and maintains its principal

place of business at 100 College Road West, Princeton, New Jersey.

9. Plaintiff RareGen provides strategic, commercialization, and promotional support for rare disease treatments. RareGen has partnered with Sandoz to launch the first generic version of treprostinil injections for the treatment of PAH. RareGen is a limited liability company that is organized under Delaware law. All of its members are residents in Virginia and North Carolina, and it maintains its principal place of business at 200 Garrett Street, Suite R, Charlottesville, Virginia.

10. Defendant United Therapeutics is a biotechnology company that markets and sells four commercial therapies in the United States to treat PAH: Remodulin® (treprostinil injection); Tyvaso® (treprostinil inhalation solution); Orenitram® (treprostinil extended-release tablets); and Adcirca® (tadalafil tablets). United Therapeutics is incorporated under Delaware law, and its principal executive offices are located at 1040 Spring Street, Silver Spring, Maryland.

11. Defendant Smiths is a leading global manufacturer of specialty medical devices. Smiths is incorporated under Delaware law, and its worldwide headquarters are located at 6000 Nathan Lane North, Minneapolis, Minnesota.

JURISDICTION AND VENUE

12. This Court has original jurisdiction over Plaintiffs' federal antitrust claims pursuant to 28 U.S.C. § 1331. Plaintiffs bring those claims under Sections 4 and 16 of the Clayton Act (15 U.S.C. §§ 15 and 26), to obtain redress for the harm

caused by Defendants' violations of Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1, 2).

13. This Court also has original jurisdiction over Plaintiffs' federal antitrust claims under 28 U.S.C. § 1337.

14. This Court has original jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1332. The matter in controversy exceeds $75,000, exclusive of interest and costs, and there is complete diversity of citizenship between Plaintiffs and Defendants.

15. This Court also has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367(a). This Court has original jurisdiction over Plaintiffs' federal antitrust claims, and Plaintiffs' state law claims arise from the same case or controversy underlying Plaintiffs' federal antitrust claims.

16. Venue is proper in this District pursuant to 15 U.S.C. § 22 because both Defendants conduct business within this District. Venue also is proper in this District under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred within this judicial district.

BEFORE GENERIC COMPETITION THERE WERE NO RESTRICTIONS ON THE SALE OR USE OF CARTRIDGES

17. The most common symptoms of PAH are shortness of breath, chest pain, exhaustion, dizziness or fainting, and heart palpitations. The New York Heart Association has created four functional classes for evaluating heart failure, and those

classes are often used to classify the severity of a PAH patient's symptoms. Class I patients have no observable symptoms. Class II patients experience symptoms when active. Class III patients experience symptoms at rest. And Class IV patients are severely affected by PAH at all times.

18. Doctors typically prescribe treprostinil injections for Class III and Class IV patients with acute PAH symptoms. According to United Therapeutics' CEO, for those patients it is "necessary to keep a continuous level of our key molecule, treprostinil, flushing through their pulmonary arteries 24/7. And the only demonstrated way to achieve this continuously with an absolutely constant level of treprostinil levels is through a parenteral delivery system."

19. Remodulin® is a parenterally administered (injected) form of treprostinil. It is administered in one of two ways: (1) under a patient's skin (subcutaneous injection); or (2) directly into a patient's veins (intravenous injection). United Therapeutics estimates that more than half of the patients being treated for PAH with Remodulin® are receiving Remodulin® through subcutaneous injections, and subcutaneous injection is the preferred method of administration for new patients. The remaining patients receive intravenous Remodulin® injections.

20. Currently, PAH patients who are prescribed subcutaneous treprostinil injections receive their Remodulin® injections only through the CADD-MS 3 pump, which is manufactured exclusively by Defendant Smiths. The CADD-MS 3 pump

is approximately the size of a cell phone. It maintains a steady flow of medication into the patient's body and remains constantly in use, 24 hours a day, seven days a week. Out of medical necessity, every few days a patient must replace his or her CADD-MS 3 pump's cartridge, which contains the patient's prescribed treprostinil dosage.

CADD-MS 3 Pump and Cartridge

21. There are no other medical devices that are currently being used to administer subcutaneous treprostinil injections in the United States.

22. PAH patient options are further limited because treprostinil requires a physician's prescription, and those prescriptions can only be filled by one of two specialty pharmacies: Accredo Health Group, Inc. ("Accredo") and CVS Specialty Pharmacy ("CVS Specialty"). Accredo and CVS Specialty provide PAH patients with the specialized equipment, training, and support services they need to receive parenterally administered PAH treatments.

23. The U.S. Food and Drug Administration ("FDA") first approved Remodulin® for subcutaneous injections in the United States in 2002.

24. Prior to the launch of Plaintiffs' generic version of injected treprostinil on March 25, 2019, there was no generic alternative to Remodulin® in the market.

25. On information and belief, at no time prior to December 2018 did Defendants ever restrict the sale or use of cartridges by mandating that they could only be used to administer Remodulin® treatments.

STATUTORY AND REGULATORY BACKGROUND

26. Before marketing a new drug in the United States, a manufacturer must obtain FDA approval for its new drug application ("NDA"). Once approved, new drugs generally are called "brand-name" drugs because they are marketed under a trade name or trademark for the drug rather than the chemical name of the drug's active ingredient.

27. Among other things, an NDA must contain technical data on the composition of the drug, including its active ingredient, the means for its manufacture, and a statement of its proposed uses. The FDA approves a new drug only if it determines, based on evidence submitted by the manufacturer, that the drug is safe and effective for its proposed use(s).

28. Congress enacted the Drug Price Competition & Patent Term Restoration Act, which is commonly known as the Hatch-Waxman Act, to increase

the availability of low-cost generic drugs by expediting the FDA approval process for generic drugs. To preserve incentives for manufacturers to invest in the development of new drugs, the Hatch-Waxman Act also provides that brand-name manufacturers may be entitled to exclusivity for new drugs for a prescribed period of time and they are given the ability to apply, under certain circumstances, to extend the patent protection for their drugs by up to an additional five years.

29. A generic drug contains the same active ingredient as the brand-name drug but typically sells at a lower price than the brand-name drug. As a result, generic drugs are frequently prescribed as a substitute for brand-name drugs in an effort to control healthcare costs, and they represent an increasing portion of the medicines used in the United States. The Generic Pharmaceutical Association (now known as the Association for Accessible Medicines) estimates that from 2001 through 2010, the nation's healthcare system saved $931 billion from the use of generic drugs. Achieving cost savings through generic substitution is critical for expensive, life-saving treatments like Remodulin®.

30. The introduction of a generic drug as an alternative to a brand-name drug typically results in a dramatic reduction in the brand-name drug's market share, and the rate of reduction is particularly dramatic in the first six months.

31. Before marketing a generic drug in the United States, a manufacturer must obtain FDA approval for an Abbreviated New Drug Application ("ANDA").

To obtain FDA approval, an ANDA applicant must show that its generic drug is as safe and effective as the approved brand-name drug.

32. Under the Hatch-Waxman Act, manufacturers of brand-name drugs are required to identify the list of patents that correspond to each approved brand-name drug, and that list of patents is published by the FDA in what is commonly known as the "Orange Book."

33. As an incentive for generic drug manufacturers to challenge invalid or unenforceable patents corresponding to brand-name drugs, the Hatch-Waxman Act awards 180 days of marketing exclusivity to the generic applicant that is first to file an ANDA (or amended ANDA) with the proper certification. The applicant that receives this marketing exclusivity is known as the "first filer."

UNITED THERAPEUTICS' PLAN TO "MAKE GENERIC BARBARIC" FAILED

34. In 2011, Sandoz submitted an ANDA to the FDA, requesting permission to market a generic version of treprostinil for use in both subcutaneous and intravenous injections. Sandoz was the "first filer" for generic treprostinil injections.

35. In its ANDA, Sandoz certified that United Therapeutics' patents related to Remodulin® were invalid or would not otherwise be infringed by its generic version of treprostinil.

36. United Therapeutics immediately sued Sandoz in this Court, claiming its patents were infringed by the generic treprostinil formulation developed by Sandoz.

37. The parties settled that suit in September 2015. Under the terms of the settlement, Sandoz was permitted to start marketing its generic treprostinil alternative in June 2018.

38. The FDA approved the Sandoz ANDA for generic treprostinil in November 2017, for both subcutaneous and intravenous injections.

39. Following United Therapeutics' patent settlement with Sandoz in 2015, Sandoz posed a competitive threat to Remodulin®. United Therapeutics began telling its investors that it expected "a risk of generic Remodulin erosion in the second half of 2018," but reassured investors that it had plans to take "a couple of steps to ameliorate that." Specifically, it planned to "make generic barbaric" by developing new, proprietary methods of administering Remodulin® injections and pushing patients and specialty pharmacies to adopt them. According to United Therapeutics' CEO, "that little mantra reminds us that our job is to advance the state of patient care so rapidly that generic technologies and generic drugs delivered to old devices will seem barbaric."

40. As part of this strategy, United Therapeutics partnered with Medtronic plc to develop an implantable pump, which it has dubbed the "RemoSynch" pump

or Implantable System for Remodulin®, to serve as an alternative to intravenous injections. Unlike the external pumps traditionally used for intravenous treatments, the Medtronic pump would be surgically implanted into the patient's body. According to United Therapeutics' CEO, that pump would "greatly diminish the opportunity for generic penetration" because patients would prefer an implantable pump, which only needed to be refreshed every few months, to an external pump that needed to be refreshed every few days. And United Therapeutics obtained a commitment from Medtronic that the new pump would only be offered "with branded treprostinil, in other words Remodulin included in it."

41. United Therapeutics initially planned for the new, implantable pump to be launched in 2017, well before Sandoz could sell its generic treprostinil injections under the terms of the patent settlement. On April 3, 2017, however, United Therapeutics announced that it would not obtain FDA approval in time to launch its pump in 2017. Without a new pump on the market before Sandoz could begin selling its generic alternative to Remodulin®, United Therapeutics faced the prospect of head-to-head competition with a cheaper, generic alternative for patients receiving intravenous injections. The RemoSynch pump was finally approved by the FDA in July 2018 (four years after the parties submitted their application), but it cannot be used with Remodulin® until Medtronic satisfies certain conditions established by the FDA, which have not yet been satisfied.

42. For the subcutaneous segment of the market, United Therapeutics implemented the same strategy by partnering with DEKA Research and Development Corporation ("DEKA") to develop a disposable Remodulin® pump, which it called the RemUnity pump. United Therapeutics intended for the RemUnity pump to replace the CADD-MS 3 pump that patients use for subcutaneous treatments. Yet again, United Therapeutics planned to rely on an exclusivity strategy to gain a leg up on generic competition with this new pump. As United Therapeutics' CEO explained, "[p]er [United Therapeutics'] agreement with DEKA, only branded Remodulin can be used in this pump."

43. DEKA and United Therapeutics filed for FDA approval of the RemUnity pump in February 2018. The RemUnity pump, however, still has not been approved by the FDA.

44. United Therapeutics has also announced a number of other projects for the development of pumps for subcutaneous administration of treprostinil that are in earlier stages of development, including the RemoLife infusion system that is being developed by Smiths and the Trevyent pump system that was acquired by United Therapeutics when it purchased SteadyMed Ltd. in August 2018. On information and belief, these new pumps will be subject to the same restrictions as the other pumps under development, *i.e.*, they will only be used with Remodulin®.

DEFENDANTS PROHIBIT PATIENTS FROM GAINING ACCESS TO GENERIC TREPROSTINIL

45. In August 2018, Sandoz and RareGen agreed to jointly market and sell generic treprostinil for subcutaneous and intravenous injections. Under that agreement, RareGen has the exclusive right to encourage the appropriate use of generic treprostinil injections, including by using Sandoz trademarks and copyrights. RareGen is responsible for establishing sales representatives and educating and supporting physicians, nurse practitioners, physician assistants, and other medical professionals with prescribing authority with respect to the benefits of generic treprostinil injections. Sandoz is responsible for maintaining a sufficient supply of generic treprostinil.

46. By late 2018, Sandoz and RareGen were preparing to commercially launch generic treprostinil for both subcutaneous and intravenous treatments. But with its new pumps awaiting FDA approval, United Therapeutics still had not come up with a way to effectively stifle competition with Plaintiffs' generic alternative in the subcutaneous segment of the market. So it turned its attention to the existing cartridges used to administer subcutaneous treprostinil injections and sought to control those devices to avoid having to compete at all. In conjunction with Smiths, United Therapeutics completely blocked potential generic competitors from delivering treprostinil to patients receiving subcutaneous injections.

47. In December 2018, Smiths began telling specialty pharmacies that it

would not sell CADD-MS 3 cartridges for use with generic treprostinil injections. Smiths told Accredo and CVS Specialty that any additional cartridges they obtained could only be used with Remodulin®, and, on information and belief, Smiths also threatened to stop selling cartridges to Accredo and CVS Specialty if they dispensed cartridges to administer generic treprostinil injections.

48. Later, when Sandoz and RareGen sought to order CADD-MS 3 cartridges from Smiths' distributors, Defendants blocked those orders as well, and told the distributors that they could only sell the cartridges to Accredo and CVS Specialty for use with Remodulin®.

49. In furtherance of Defendants' anticompetitive scheme, sometime after Sandoz' ANDA became public, but before Sandoz and RareGen were ready to start selling generic treprostinil, Smiths sold all of its remaining cartridges and the resin necessary to manufacture the cartridges to United Therapeutics under a secret agreement.

50. Defendants have cornered the market. They have enough cartridges and resin to supply the entire market—for subcutaneous injections of Remodulin® and for generic treprostinil. That entire supply, however, is now dedicated to Remodulin®. The impact of Defendants' arrangement is clear: it blocks generic entry and maintains high prices for Remodulin®. Specialty pharmacies already own sufficient pumps to administer generic treprostinil treatments, but because of

Defendants' restrictions they—and more importantly, patients—cannot obtain cartridges to use with generic treprostinil. As a result, United Therapeutics has maintained its monopoly over a large segment of the market that it does not deserve and has not earned.

51. The existence of this secret arrangement between United Therapeutics and Smiths was recently confirmed in United Therapeutics' 10-K filing for its 2018 fiscal year, where United Therapeutics stated:

> Smiths Medical manufactures the pumps used by most patients in the United States to administer Remodulin, including the Smiths CADD® MS-3 pump used to deliver subcutaneous Remodulin. In 2015, Smiths Medical notified us that it was planning to discontinue the manufacture of the CADD MS-3 pumps and associated cartridges. We entered into an agreement with Smiths Medical to fund the manufacture of a further supply of CADD MS-3 pumps and cartridges for use with branded Remodulin only. We anticipate this supply will be sufficient to ensure continued support of subcutaneous Remodulin for several years, and are working with Smiths Medical to develop a next-generation infusion system called RemoLife prior to the exhaustion of the available CADD MS-3 supply.

52. As a result of Defendants' anticompetitive conduct, Sandoz and RareGen are unable to sell their cheaper, generic alternative to Remodulin® for use in subcutaneous treatments. For patients receiving subcutaneous injections, Remodulin® is their only option.

RELEVANT PRODUCT MARKETS

53. Three classes of drugs have been approved by the FDA to treat PAH. They are called: (1) Endothelin Receptor Antagonists ("ERAs");

(2) Phospodiesterase Type 5 inhibitors ("PDE-5s"), and (3) Prostacyclins.

54. The active ingredient in Remodulin® is treprostinil, which is a synthetic form of prostacyclin.

55. The treatment program used by a PAH patient (*i.e.*, the drug and delivery mechanism) is based on the severity of the patient's symptoms and the treating physician's judgment. The selection of one drug class over another, or of a particular administration method, is not based on the underlying price of the treatments. Thus, a small, but significant, and non-transitory increase in the price of one class of drugs would not cause treating physicians and patients to substitute in significant numbers to a different class of drugs; and a small, but significant, and non-transitory increase in the price of one administration method would not cause treating physicians and patients to substitute in significant numbers to a different administration method.

56. ERA and PDE-5 treatments are not reasonable substitutes for prostacyclin treatments because they are indicated for less severe forms of PAH. As a patient's symptoms become worse, they will typically progress to prostacyclin treatments. As United Therapeutics' CEO has explained:

> There are the PDE-5 inhibitors of which the two brand names that are most well-known, Viagra and Cialis, are of that category. And those drugs have been rebranded to be used in pulmonary hypertension. You have to take them every day for the rest of your life.

> And they are able to effectuate some dilation in those distal pulmonary arteries and help patients for a while. But almost every patient disease ends up progressing through the benefits given by the PDE-5 inhibitors.
>
> So, I will also mention that PD[E]-5 inhibitors are the least expensive drugs for treating this disease and are generally the first line therapy provided to the patient. Once their disease progresses through these PDE-5 inhibitors, the patient[s] next have a line of drugs called endothelium receptor antagonists, or ERAs for short. . . .
>
> They help the group one pulmonary arterial hypertension patient for a while. But as with the PDE-5s, the patient disease progresses through the benefits of the ERAs. And on average the patients will stay on an ERA for something like one to two years before their disease has progressed and they need yet a stronger medicine.
>
> And then at the end of the – at the end of this progression is a third class of medicines of what are called the prostacyclin class. . . .

57. Within the class of prostacyclin-based PAH treatments, there are at least two relevant antitrust product markets that are affected by Defendants' unlawful conduct: (1) the market for subcutaneously injected treprostinil; and (2) the market for injected prostacyclins.

Subcutaneously Injected Treprostinil

58. Prostacyclin-based therapies administered by injection are highly differentiated. At one end of the spectrum are treatments based on epoprostenol (which include the brand-name drugs Flolan® and Veletri®) and at the other end of the spectrum are treatments based on treprostinil (such as Remodulin®). There are significant differences between the two sets of medications that make one of them,

or the other, the best alternative for a particular patient that needs to receive prostacyclin injections.

59. As United Therapeutics explained in its latest 10-K filing with the SEC:

> Remodulin is stable at room temperature, so it does not need to be cooled during infusion and patients do not need to use cooling packs or refrigeration to keep it stable. Treprostinil is highly soluble and highly potent, which enables us to manufacture Remodulin in concentrated solutions. This allows therapeutic concentrations of Remodulin to be delivered at very low flow rates via miniaturized infusion pumps for both subcutaneous and intravenous infusion. Remodulin can be continuously infused for up to 48 hours intravenously or 72 hours subcutaneously before refilling the external infusion pump. This profile contrasts favorably with the other continuously infused prostacyclin therapies in the market—Flolan®, Veletri® and generic epoprostenol.
>
> Flolan and generic epoprostenol are not stable at room temperature (and therefore require refrigeration or the use of cooling packs), but Veletri may be stable at room temperature depending on its concentration. Flolan, generic epoprostenol, and Veletri have shorter half-lives than Remodulin, requiring mixing prior to pump refills. None of these competitive products may be administered via subcutaneous infusion, and therefore may only be delivered intravenously.

60. Because of the substantial differences between injected treprostinil treatments and those based on epoprostenol, treprostinil is the only PAH treatment that can be administered through subcutaneous injections in the United States today.

61. There are approximately 2,000 patients in the United States who are currently being treated for PAH with subcutaneous Remodulin® injections. Those patients have been prescribed Remodulin® by their treating physicians and their treatment program relies on subcutaneous injections using the CADD-MS 3 pump.

Those patients will not switch to other PAH treatments in response to a small, but significant, and non-transitory increase in the price of subcutaneously injected treprostinil.

62. Subcutaneously injected treprostinil therefore constitutes a relevant antitrust product market.

Injected Prostacyclins

63. Prostacyclin-based treatments for PAH can be administered through (1) inhaled treatments, such as inhaled treprostinil (including the branded drug Tyvaso®, which is sold by United Therapeutics); (2) oral treatments, such as treprostinil in tablet form (including the branded drug Orenitram®, also sold by United Therapeutics); or (3) injected treatments (such as Remodulin®).

64. Inhaled and oral prostacyclin treatments are not reasonable substitutes for injected prostacyclin treatments.

65. As United Therapeutics' CEO has explained, whether patients "go onto Orenitram first and then Tyvaso, or Tyvaso first and then Remodulin, or straight to Remodulin" is "simply a consequence of their doctor's judgment as to how much prostacyclin they require and in what form."

66. If a patient is diagnosed with PAH before their symptoms become severe, they typically will start a treatment program based on oral prostacyclins, and

progress over time to other forms of treatment as their symptoms change. Again, United Therapeutics' CEO explained:

> [T]here is an entire family of the most potent treatments for pulmonary hypertension across the cyclin family that you can start with orally. As the patient's disease progresses, you can move to an inhaled therapy for them, which is less invasive . . . than parenteral, but still getting the medicine more directly to where it's needed in the distal portions of the pulmonary vascular bed via Tyvaso. And then finally, if the patients and disease continues to progress, which unfortunately the vast majority [do], the kind of drugs you can transition the patient on to parenteral, Remodulin, either subcutaneous or intravenous.

67. According to United Therapeutics' CEO, Remodulin® "is the medicine that physicians reach for when patients are struggling with managing their pulmonary hypertension due to the oral treatments not being able to halt the progression of the disease."

68. For all these reasons, patients who have been prescribed injected prostacyclin treatments will not switch to other prostacyclin treatments in response to a small, but significant, and non-transitory increase in the price of injected prostacyclin.

69. Injected prostacyclins therefore constitute a relevant antitrust product market.

RELEVANT GEOGRAPHIC MARKET

70. The relevant geographic market is no larger than the United States. Due to FDA regulations and the importance of this life-preserving treatment, a small, but

significant, and non-transitory increase in the price of subcutaneously injected treprostinil or injected prostacyclins would not cause treating physicians and patients to substitute in significant numbers to other treatments that are not available in the United States.

MARKET SHARES

71. Before the entry of generic competition, United Therapeutics sold 100% of the treprostinil administered through subcutaneous injections in the United States, and as a result of the restrictions related to the CADD-MS 3 cartridges, United Therapeutics continues to sell 100% of the treprostinil administered through subcutaneous injections in the United States.

72. The market for injected prostacyclins is highly concentrated in the United States, with United Therapeutics holding a share of the market in excess of 70%. In 2016, for example, United Therapeutics estimated that it "own[ed] about 82% share in the parenteral market." And as of June 2018, United Therapeutics boasted "Remodulin is the most prescribed continuous pump therapy for WHO Group 1 pulmonary arterial hypertension (PAH). Seven out of 10 patients on continuous therapy are prescribed Remodulin." "WHO Group 1" refers to PAH caused by arteries in the lungs becoming narrowed, thickened or stiff, which is the type of PAH treated by injected prostacyclins like Remodulin®.

BARRIERS TO ENTRY

73. Barriers to entry into the relevant antitrust markets are high. In the United States, prescription drugs cannot be marketed and sold without FDA approval. Patients in the United States cannot be treated with prescription medications that have not been approved by the FDA. Obtaining FDA approval for new injected prostacyclin treatments is difficult and expensive. There are currently only five forms of injected prostacyclins that have been approved by the FDA (Remodulin®, Flolan®, Veletri®, generic epoprostenol and generic treprostinil).

74. Even with FDA approval to start marketing generic treprostinil, no firm can sell their generic alternative to Remodulin® to treat patients who are being treated with subcutaneous injections. Defendants' unlawful restrictions have entirely foreclosed that segment of the market.

ANTICOMPETITIVE EFFECTS AND ANTITRUST INJURY

75. There are approximately 2,000 patients in the United States that are currently being treated for PAH with subcutaneous Remodulin® injections. Those patients have been prescribed Remodulin® by their treating physicians and their treatment program relies on subcutaneous injections using the CADD-MS 3 pump. Today, none of those patients can use generic treprostinil as an alternative to Remodulin® for subcutaneous injections because of Defendants' anticompetitive conduct.

76. Plaintiffs' generic treprostinil is being offered at a substantial discount to Remodulin®. Thus, as a result of Defendants' anticompetitive conduct, patients are being deprived of a lower-cost, generic form of treprostinil that can be administered subcutaneously.

77. Defendants have impaired competition from Sandoz and RareGen by artificially restricting the number of alternatives for subcutaneous treprostinil injections, which has allowed United Therapeutics to maintain high prices for Remodulin®. Competition has therefore been harmed and the injuries sustained by Sandoz and RareGen are of the type the antitrust laws were meant to prevent; they flow from the harm to competition caused by Defendants' unlawful conduct.

CAUSES OF ACTION

COUNT 1: RESTRAINT OF TRADE (15 U.S.C. § 1)

78. Sandoz and RareGen incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

79. Defendants entered into contracts, combinations in the form of trust or otherwise, or conspiracies, in restraint of trade or commerce among the several States. Those contracts, combinations, or conspiracies are unreasonable restraints of trade. The relevant contracts, combinations, or conspiracies include at least: (1) the multi-year exclusive agreement between United Therapeutics and Smiths whereby Smiths will exclusively service United Therapeutics' Remodulin®

customers; (2) Smiths' agreement to sell all remaining resin used to make the CADD-MS 3 cartridges to United Therapeutics in order to prevent competitors from manufacturing their own cartridges for subcutaneous administration of treprostinil; and (3) Defendants' agreements requiring that CADD-MS 3 cartridges only be used with Remodulin®, thereby prohibiting cartridges from being used to administer generic treprostinil injections.

80. Defendants' conduct has no legitimate business purpose or pro-competitive effect.

81. Defendants' conduct has had a substantial effect on interstate commerce.

82. Sandoz and RareGen were injured in their business or property as a result of Defendants' anticompetitive conduct and they have suffered and will suffer injury of the type that the antitrust laws were intended to prevent.

COUNT 2: MONOPOLIZATION (15 U.S.C. § 2)

83. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

84. Defendants have monopolized or combined or conspired to monopolize the trade or commerce among the several States. The trade or commerce that Defendants have monopolized or conspired to monopolize includes the markets for injected prostacyclins and/or subcutaneously injected treprostinil. Defendants'

conduct has excluded competition from Sandoz and RareGen in those relevant markets, where they hold market shares in excess of 70%. Defendants' exclusionary acts include, *inter alia*, the following: (1) the multi-year exclusive agreement between United Therapeutics and Smiths whereby Smiths will exclusively service United Therapeutics' Remodulin® customers; (2) Smiths' agreement to sell all remaining resin used to make the CADD-MS 3 cartridges to United Therapeutics in order to prevent competitors from manufacturing their own cartridges for subcutaneous administration of treprostinil; and (3) Defendants' agreements requiring that CADD-MS 3 cartridges only be used with Remodulin®, thereby prohibiting cartridges from being used to administer generic treprostinil injections.

85. Defendants' conduct has no legitimate business purpose or pro-competitive effect.

86. Defendants' conduct has had a substantial effect on interstate commerce.

87. Sandoz and RareGen were injured in their business or property as a result of Defendants' anticompetitive conduct and they have suffered and will suffer injury of the type that the antitrust laws were intended to prevent.

COUNT 3: RESTRAINT OF TRADE (N.J. Stat. Ann. § 56:9-3)

88. Sandoz and RareGen incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

89. Defendants entered into contracts, combinations in the form of trust or otherwise, or conspiracies, in restraint of trade or commerce in New Jersey. Those contracts, combinations, or conspiracies are unreasonable restraints of trade. The relevant contracts, combinations, or conspiracies include at least: (1) the multi-year exclusive agreement between United Therapeutics and Smiths whereby Smiths will exclusively service United Therapeutics' Remodulin® customers; (2) Smiths' agreement to sell all remaining resin used to make the CADD-MS 3 cartridges to United Therapeutics in order to prevent competitors from manufacturing their own cartridges for subcutaneous administration of treprostinil; and (3) Defendants' agreements requiring that CADD-MS 3 cartridges only be used with Remodulin®, thereby prohibiting cartridges from being used to administer generic treprostinil injections.

90. Defendants' conduct has no legitimate business purpose or pro-competitive effect.

91. Sandoz and RareGen were injured in their business or property as a result of Defendants' anticompetitive conduct and they have suffered and will suffer injury of the type that the antitrust laws were intended to prevent.

COUNT 4: RESTRAINT OF TRADE (N.C. Gen. Stat. § 75-1)

92. Sandoz and RareGen incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

93. Defendants entered into contracts, combinations in the form of trust or otherwise, or conspiracies, in restraint of trade or commerce in North Carolina. Those contracts, combinations, or conspiracies are unreasonable restraints of trade. The relevant contracts, combinations, or conspiracies include at least: (1) the multi-year exclusive agreement between United Therapeutics and Smiths whereby Smiths will exclusively service United Therapeutics' Remodulin® customers; (2) Smiths' agreement to sell all remaining resin used to make the CADD-MS 3 cartridges to United Therapeutics in order to prevent competitors from manufacturing their own cartridges for subcutaneous administration of treprostinil; and (3) Defendants' agreements requiring that CADD-MS 3 cartridges only be used with Remodulin®, thereby prohibiting cartridges from being used to administer generic treprostinil injections.

94. Defendants' conduct has no legitimate business purpose or pro-competitive effect.

95. Sandoz and RareGen were injured in their business or property as a result of Defendants' anticompetitive conduct and they have suffered and will suffer injury of the type that the antitrust laws were intended to prevent.

COUNT 5: UNFAIR TRADE PRACTICES (N.C. Gen. Stat. § 75-1.1)

96. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

97. By their conduct, Defendants have engaged in an unfair act or practice. Defendants' conduct offends established public policy and it is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers.

98. Defendants' conduct was in or had an effect on commerce.

99. Sandoz and RareGen were injured in their business or property as a result of Defendants' conduct.

COUNT 6: TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

100. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

101. Plaintiffs sell and distribute generic injected treprostinil to Accredo and CVS Specialty. They have been marketing generic injected treprostinil to Accredo and CVS to be used in both intravenous and subcutaneous PAH treatments.

102. Defendants have intentionally interfered with those business relationships by prohibiting Accredo and CVS from administering generic treprostinil through subcutaneous injections with cartridges manufactured for use in the CADD-MS 3 pump. There is no excuse or justification for those restrictions.

103. As a result of Defendants' intentional interference, Plaintiffs have not been able to sell generic treprostinil to Accredo and CVS for subcutaneous treatments. Absent Defendants' wrongful conduct, there is a reasonable likelihood that they would have been able to sell generic treprostinil for subcutaneous

treatments. Plaintiffs therefore have been damaged by Defendants' wrongful conduct.

DEMAND FOR JURY TRIAL

104. Sandoz and RareGen hereby demand a jury trial on all of their claims.

PRAYER FOR RELIEF

105. Sandoz and RareGen respectfully pray for the following relief:

a. a judgment finding that Defendants violated 15 U.S.C. § 1;

b. a judgment finding that Defendants violated 15 U.S.C. § 2;

c. a judgment finding that Defendants violated N.J. Stat. Ann. § 56:9-3;

d. a judgment finding that Defendants violated N.C. Gen. Stat. § 75-1;

e. a judgment finding that Defendants violated N.C. Gen. Stat. § 75-1.1;

f. a judgment finding that Defendants tortiously interfered with Plaintiffs' relationships with specialty pharmacies and patients;

g. preliminary and permanent injunctive relief;

h. compensatory damages, treble damages, costs, and attorneys' fees;

i. pre-judgment interest and post-judgment interest to the full extent allowed under the law; and

j. any further relief the Court may deem just and proper.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

The undersigned hereby certify that the matter in controversy in this suit is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: April 16, 2019 Respectfully submitted,

By: */s/ Thomas D. Pease*

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